

EFFECT OF WEIGHT LOSS TRAINING PROTOCOL USING TWO DIFFERENT TREADMILLS FOR OBESE INDIVIDUALS

by

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A thesis

submitted in partial fulfillment

of the requirements for the degree of

Master of Science in Exercise and Sport Studies

Boise State University

August 2014

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BOISE STATE UNIVERSITY GRADUATE COLLEGE

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Thesis Title: Effect of Weight Loss Training Protocol Using Two Different Treadmills
for Obese Individuals

Date of Final Oral Examination: 02 May 2014

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ABSTRACT

The AlterG Anti-Gravity Treadmill allows individuals to walk at reduced body weight by using lower body positive pressure (LBPP). **PURPOSE:** The purpose of this study was to discern if the AlterG Anti-Gravity Treadmill was an effective tool to use in a weight loss walking program with obese individuals when compared to walking on a traditional treadmill. **METHODS:** Fifteen male ($n = 3$) and female ($n = 12$) obese participants, aged 18-55 years old with an average body mass index [BMI] $\geq 30 \text{ kg/m}^2$, were randomly assigned to the AlterG treadmill (AlterG; $n = 6$) and traditional treadmill (TT; $n = 9$). Participants followed an 18-week (three 6-week phases) weight loss walking protocol and exercised 3 days a week. Each 6-week phase increased in intensity and duration, and by Phase 3 participants were walking at an intensity of 60-85% HRmax for 60 minutes. The participant's weight, BMI, and body fat percentage (BFP) were recorded during the program. **RESULTS:** There was no significant overall weight loss difference determined between the two groups. The AlterG and the TT group lost an average of 2.33 kg and 2.14 kg, respectively. Similarly, no significant overall differences in BMI and BFP were found between the two groups. Significant differences were found among the three phases of the weight loss intervention for weight loss ($p = 0.024$), BMI reduction ($p = 0.021$), and BFP reduction ($p < 0.0005$). Each group exhibited significant decreases in weight, BMI, and BFP by the conclusion of the study. **CONCLUSION:** This study demonstrated that the walking protocol used with the AlterG Anti-Gravity Treadmill was

effective in producing significant weight loss, decreased BMI, and reduced percent body fat in obese individuals.

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CHAPTER ONE: INTRODUCTION

Obesity

Obesity, defined as a body mass index (BMI, calculated as weight in kilograms divided by height in meters squared) of 30 kg/m² or greater, is a growing trend, especially in the United States. Obesity is the second leading cause of death behind tobacco usage and cigarette smoking.¹⁻⁷ It is a medical problem that can lead to numerous complications such as diabetes, high blood pressure, high cholesterol, and increased risk of cardiovascular disease across all ethnic and age groups.^{4,8} Obesity rates, as of 2009-2010, were 35.5% and 35.8% for women and men, respectively, and the prevalence of obesity is still high and increasing in certain ethnic groups, specifically non-Hispanic Black women and Mexican American women.⁶ National studies have indicated that within 15 years, 80% of all American adults will be overweight or obese if weight loss measures such as dietary intake and exercise are not utilized.⁹

Physical inactivity has been found to be the leading cause of cardiovascular and metabolic conditions, such as obesity, diabetes, metabolic syndrome, hypertension, and cardiovascular disease.⁹ Approximately 17% of adults are inactive and 41% of adults are not getting a sufficient amount of exercise.⁹ An insufficient amount of physical activity or exercise is considered less than 2.5 hours per week of moderate activity with the recommended amount of exercise being 3 to 3.5 hours per week of moderate activity.⁹

There is substantial evidence to suggest that increasing physical activity would reduce the amount of cardiovascular and metabolic disorders.⁹ More specifically, an inverse relationship has been demonstrated between exercise and premature mortality, cardiovascular disease, hypertension, stroke, osteoporosis, diabetes, metabolic syndrome, obesity, various types of cancers, such as colon and breast cancer, depression, falls, and functional and cognitive health.¹ Overall, it is critical for obese individuals to engage in regular physical activities and exercise to reduce the potential for developing various health-related illnesses and complications of obesity.

Musculoskeletal Pain and Obesity

Increasing physical activity levels with obese individuals is often difficult. One of the challenges faced by this population is the additional weight that is placed on the hips, knees, and ankles when performing walking or jumping activities. One of the musculoskeletal complications of obesity is osteoarthritis, especially in the lower extremities.¹⁰ In addition, the lack of lower extremity strength often observed in obese individuals may amplify the potential to develop osteoarthritis, especially in the knee.¹⁰ Obesity can also cause several orthopedic disorders and can biomechanically change gait patterns due to excessive weight-bearing forces.¹⁰ Impaired gait patterns frequently develop to compensate for a lack of leg strength, which further compounds the pain obese individuals may experience while walking or exercising.¹⁰ Fortunately, there are a variety of interventions and treatment options available to aid in weight reduction and reduce the prevalence of osteoarthritis, especially found in the knee.¹⁰

Weight Loss Options

One treatment option for obese individuals is to undergo bariatric surgery, such as gastric bypass surgery or gastric band surgery. These types of surgeries limit the amount of food that can be consumed or change how food is digested.¹¹ Whatever the type of surgery, most people lose weight quickly when choosing this option. Substantial weight loss from bariatric surgery has also been found to reduce musculoskeletal pain and improve gait mechanics.¹¹ While initial weight loss is certain, there are potential complications associated with bariatric surgery such as bleeding, infection, blood clots, poor food absorption, and hernias.¹¹ In addition, bariatric surgery is expensive, ranging from \$20,000 to \$30,000.¹¹

Successful weight loss for obese individuals has been shown to occur through an increase in exercise, an altered diet, and the use of weight loss medications.¹² Unfortunately, diets can be hard to adhere to and maintain long-term, most weight loss medications can produce negative or unwanted side effects, and medications are not always cost efficient to continue over a period of time.¹² Exercise has shown to be the safest and most successful in producing desired weight loss.¹² Regular exercise can reduce the negative effects of obesity by decreasing stress, decreasing weight, and reducing the risks for diabetes, heart disease, hypertension, and all-cause mortality rates.^{1,2,13} Even when no weight loss is seen, regular exercise has been shown to increase cardiovascular fitness levels, decrease stress, and reduce the risks for heart disease. Weight loss of 5 – 10% body weight has been shown to produce more substantial health benefits such as reducing the risk for chronic diseases including diabetes, heart disease, many forms of cancer, and numerous musculoskeletal problems.¹

Low impact exercises have been used successfully with obese individuals. Swimming is a non-weight bearing activity and has been shown to be an effective form of exercise and weight loss.¹⁴ In addition, because walking or swimming in water decreases impact on the lower extremities, joint pain can be reduced.¹⁵ However, because of the lack of weight bearing while exercising in water, swimming has been shown to produce no statistically significant increases in peak bone mass or bone structures.¹⁴ Conversely, weight-bearing activities on dry land have been shown to increase and maintain peak bone mass as well as optimize bone structure.¹⁴ Moreover, while swimming may be a beneficial exercise option for those who are obese, pool availability and the psychological effects of wearing a bathing suit in front of others often make swimming a questionable choice.¹⁴

In order to incorporate more weight-bearing activities for obese individuals, modified impact exercise equipment have been designed. Various types of treadmills have been developed to help support the weight of obese individuals while walking. Harness supported treadmill walking was first used for patients as way of decreasing loads in order to heal tissues, conserve energy, and reduce pain.¹⁵ Harness supported treadmills allowed individuals to rehabilitate injuries within their functional capacity at lower energy cost, yet still produced significant cardiovascular conditioning.¹⁵ More recently, the National Aeronautics and Space Administration (NASA) developed a treadmill that is located on board the International Space Station and is designed to allow astronauts to run without vibrating delicate microgravity science experiments in adjacent labs.¹⁶ Differential Air Pressure (DAP), created by NASA's treadmill, is used to "weight" the individual harnessed into the treadmill.¹⁶ This creates lower body negative pressure

(LBNP) inside the chamber to pull fluids into the lower extremity (simulate gravity) during the microgravity of spaceflight.^{16,17}

Based on the advances made by NASA using LBNP, the AlterG Company reversed the pressure (lower body positive pressure, LBPP),¹⁷ to reduce weight in normal gravity situations and created the AlterG Anti-Gravity Treadmill. With LBPP exercise, the normal (lifting) force is equal to the pressure differences inside and outside the chamber multiplied by the cross-sectional area of the waist seal and reduces the ground reaction forces (GRFs) proportional to the amount of unweighting selected.^{16,17} This has been approved as a clinical rehabilitation treadmill that allows an individual to exercise while effectively unweighting themselves down to 20% of their actual body weight.¹⁷ The benefit of this unweighting capability is to reduce the stress and the impact forces on the lower extremities and preserve or regain proper gait mechanics as well as proper muscle firing and recruitment patterns in clinical and rehabilitation settings.¹⁷ Based on the function of the AlterG Anti-Gravity Treadmill, it could be used as a weight-reduction device to lessen the incidence of musculoskeletal pain in the lower extremities while walking.

Need for Study

Although there are many treatment and exercise options available for obese individuals to consider when beginning a weight reduction program, the AlterG Anti-Gravity Treadmill appears to be a beneficial alternative. The AlterG Anti-Gravity Treadmill allows obese individuals to walk at lower percentages of their body weight with the assistance of LBPP. The special feature of LBPP helps reduce the actual weight placed on lower extremities and decreases the incidence of musculoskeletal pain that is

typically seen in obese individuals when involved in weight-bearing exercises.^{10,11,17} In addition, walking on the AlterG treadmill is a weight-bearing activity, which will maintain bone mineral density. Finally, the ability to walk and exercise without the added stress to soft tissue and joints could result in prolonged exercise sessions and extended opportunities to reduce body weight in the fight against obesity. However, there is insufficient evidence to support the effective use of the AlterG treadmill as a weight loss tool with obese individuals. This pilot study will test weight-loss outcomes of a walking program on the AlterG treadmill for obese individuals.

Purpose of Study

Therefore, the purpose of this study is to discern if the AlterG Anti-Gravity Treadmill is an effective tool to use in a weight loss walking program when compared to walking on a traditional treadmill.

Research Hypothesis

It was hypothesized that (1) regular use of the AlterG Anti-Gravity Treadmill would result in statistically significant exercise-induced weight loss in obese individuals, (2) the traditional treadmill group (TT) would lose more weight than the AlterG Anti-Gravity Treadmill (AlterG) group at the conclusion of the intervention, (3) the AlterG group would have lower Numeric Pain Scores (NPS) while walking than those walking on a traditional treadmill, and (4) the AlterG group would have higher compliance rates during the intervention than the TT group.

Significance of Study

The results of this study will be significant as the data will provide preliminary evidence for using the AlterG Anti-Gravity Treadmill with obese individuals in a weight loss program. The benefits to weight loss are well-documented and may include decreased risk of heart disease and diabetes, increased capacity for activities of daily living, decreased risk of musculoskeletal diseases, and enhanced self-image and general appearance.¹

Study Limitations

This research involved collecting data based on a weight-loss walking program in a laboratory setting. While participants were asked to maintain their normal, daily schedule and eating patterns during this study, additional physical activity or diet changes initiated by the participants could affect the results. Every attempt was made to help participants maintain consistent involvement in the study; however, unforeseen circumstances may prevent some individuals from completing the study. Due to the availability of one AlterG Anti-Gravity Treadmill, one traditional treadmill, and a sole exercise technician, the number of participants in this study was limited, which may reduce the statistical power of the results. Finally, because obese individuals from this study were recruited from the Boise, Idaho area, the results of this study may not be generalized to other obese individuals living in other communities.

Operational Definitions

- **Exercise:** defined as planned skeletal muscle movement that results in caloric expenditure¹

- **Obesity:** defined as a body mass index (BMI) of 30 kg/m^2 or greater, which is calculated as weight in kilograms divided by height in meters squared ⁶
- **Pain level:** defined as the level of physical suffering of discomfort caused by illness or injury as measured by the numeric pain scale (NPS) ¹⁸
- **Rate of perceived exertion (RPE):** defined as the level of physical work being performed as measured by the modified Borg scale ¹⁹

CHAPTER TWO: LITERATURE REVIEW

The scope of the literature review will include the physiological and musculoskeletal benefits of exercise, effects of exercise on weight loss, as well as the benefits and significance of anti-gravity exercise. Studies were included in the literature review if they discussed either weight loss programs or antigravity exercise for weight loss or rehabilitative purposes.

Physiological and Musculoskeletal Benefits

Regular exercise has many physiological benefits, especially when used to combat obesity. Engagement in regular exercise helps to prevent or manage high blood pressure as well as manage cholesterol levels.^{1,20,21} Regular exercise can raise high density lipoprotein (HDL) cholesterol, which is known as the “good cholesterol,” and regular exercise can decrease low density lipoprotein (LDL) cholesterol, which is known as the “bad cholesterol.”^{1,20,21} Maintaining appropriate cholesterol levels helps to manage plaque build-up, which explains why regular exercise can reduce risks for chronic diseases such as cardiovascular disease, diabetes, and certain cancers.^{1,20,21} The American Heart Association (AHA) states that “aerobic exercise capacity is one of the single best predictors of risk for future adverse events in apparently healthy individuals, those at increased risk for CVD, and virtually all patient populations independent of other traditional risk factors.”^{20(p.883)}

Regular exercise can also reduce body weight through an increase in caloric expenditure. For example, walking a mile burns close to 100 calories.¹ A reduction in weight has been shown to reduce the risks for diabetes, heart disease, and all-cause mortality rates due to less adipose tissue.¹⁻³ Even without associated weight loss, exercise has been shown to increase cardiovascular fitness levels, decrease stress, and reduce the risks for heart disease.¹⁻³ However, a weight loss of 5 – 10% body weight, in conjunction with exercise, has been shown to produce more substantial health benefits such as reducing the risk for chronic diseases including diabetes, heart disease, many forms of cancer, and numerous musculoskeletal problems.¹⁻³

Regular exercise also has many musculoskeletal benefits. Bone density responds to regular exercise by increasing peak bone mass.²¹ Maximum bone density is important in order to decrease the risks of osteoporosis, and is especially important in women who are more susceptible to develop osteoporosis.²¹ Bone mass generally peaks in the third decade of life and thereafter slowly decreases.²¹ Regular exercise can prevent or slow bone loss by building strength in the muscles to improve coordination and balance as well as reduce the prevalence of falls and fractures.²¹ The best form of exercise to increase bone density is weight-bearing activities due to the increased work against gravity.²¹ Examples of weight-bearing activities include walking, jogging, and climbing stairs. Non-weight bearing activities, such as swimming and most bicycling activities, are still beneficial in producing cardiovascular benefits; however, they do not increase bone density.²¹

Engagement in regular exercise will result in increased muscle mass also known as lean body mass as well as increased muscular strength.¹ Increases in muscle mass and

strength are beneficial for several reasons. More muscle mass means an increased metabolism as muscle burns more calories than fat, muscle naturally burns more calories than fat in order to maintain proper functional capability, and an increased muscle strength leads to a reduction in injuries and improves balance.¹ Finally, increases in both muscle mass and strength also help improve mood and better sleep due to increases in energy from the extra calories burned compared to fat calories.¹

Exercise Guidelines for Weight Loss

The American College of Sports Medicine (ACSM) states that energy expenditure must exceed energy intake for weight loss to occur; in basic terms, individuals must burn more calories than they eat to lose weight.^{1,20,21} There are three methods for achieving this negative caloric balance and weight loss: (1) consume fewer calories, (2) expend more calories, or (3) a combination of consuming fewer and expending more calories. Exercise plays a key role in methods 2 and 3.

ACSM has published exercise prescription guidelines for weight loss and maintenance.¹ These guidelines are based on the amount of energy it takes to perform various physical activities. Metabolic Equivalents (METs) are a physiological measure used to express the energy cost of physical activity and are used by exercise physiologists to determine what activities are appropriate for individuals given their current cardiovascular fitness level.¹ For example, one MET equals the amount of energy expended at rest, light intensity training is considered as 1.1 - 2.9 METs, moderate training intensity as 3.0 - 5.9 METs, and vigorous training intensity as ≥ 6 METs.^{1,20,22} A higher MET level indicates an increase in energy cost resulting in a greater caloric expenditure and potential weight loss. Research has also shown that every 1-MET

increase in aerobic capacity resulted in a 13% decrease in all-cause mortality and a 15% decrease in cardiovascular events.²⁰

All training prescriptions follow a general program, often referred to as FITT (frequency, intensity, time, and type). Following the FITT principle, frequency refers to how often an exercise routine is performed each week. It is recommended to exercise five or more days per week.¹ Intensity represents the force or effort used during exercise. A moderate-to-vigorous intensity level, which could also be described as 40 – 60% heart rate reserve (HRR), is recommended to enhance cardiovascular health.¹ The first T in FITT indicates how much time should be spent in an exercise session. Each exercise session should last 30 – 60 minutes per day for a minimum of 150 minutes per week and progress to 300 minutes per week.¹ It is also effective to accumulate intermittent exercises of at least 10 minutes before progressing to a continuous bout of 30 – 60 minutes of exercise.¹ Accumulated exercise time is sometimes recommended for individuals who are just starting with a new exercise program to help build a baseline of cardiovascular fitness.¹ Finally, the last T in FITT refers to the type of activity and should include a balanced program of cardiovascular and resistance training exercises.¹

Specific exercise guidelines have also been established for overweight and obese populations. Based on these guidelines, it is recommended that individuals who are overweight or obese try to exercise five to seven days per week with intensity levels at a moderate level, which would equate to 40 – 60% heart rate reserve (HRR).¹ It has been suggested that emphasis should be placed on duration and frequency rather than intensity; therefore, the ACSM has recommended that obese individuals gradually work towards 45 to 60 minutes of exercise. Longer durations of exercise at lower intensities have been

shown to shift from a glycogen fuel source to fat stores after 30 minutes. For long-term weight loss and weight management, it has been emphasized that obese individuals exercise for a total of 250-300 minutes per week.¹ Accumulated exercise broken into 10-minute sessions is recommended for obese individuals who were previously sedentary and are just starting a new exercise program.¹ Finally, the type of activity should include a balanced program of cardiovascular and resistance training exercises.¹

The ACSM position stand on weight loss states that a safe level of weight loss is about 1-2 kg/week (2-3 pounds).²² The National Strength and Conditioning Association (NSCA) recommends “an initial weight loss goal of 5-10% body weight over the course of six months and defines successful weight maintenance as a weight regain of ≤ 3 kg in two years and sustained reduction in waist circumference of at least four cm.”^{2(p.47)} Elements of weight loss involves body composition, which is made up of lean mass (LM) and fat mass (FM). Lean mass consists of bones, organs, and muscles whereas fat mass consists of fat only.¹ Body fat percentage can be calculated using the amount of LM and the amount of FM to determine the percent of FM on the body. In terms of losing weight, fat mass (FM) can be changed the most, with variability of body fat range from 6-60% of total body weight.^{23,24} The recommended body fat percentage for men ranges between 10% - 22%, and the recommended body fat percentage for women ranges between 20% - 32%.¹

An additional way to determine body composition is the use of the Body Mass Index (BMI). BMI is used to assess gender-specific weight relative to height and is calculated as weight (in kilograms) divided by height (in meters) squared.¹ The classifications for BMI are underweight $< 18.5 \text{ kg/m}^2$, normal $18.5\text{-}24.9 \text{ kg/m}^2$,

overweight 25.0-29.9 kg/m², obesity class I 30.0-34.9 kg/m², obesity class II 35.0-39.9 kg/m², and obesity class III ≥ 40.0 kg/m².¹ Although BMI fails to discern between lean mass, fat mass, or bone, a BMI of ≥ 30.0 kg/m² is still associated with increased risks of hypertension, sleep apnea, Type 2 diabetes, CVD, and higher mortality rates.¹

Finally, the ACSM emphasizes the difference between physical activity (PA) for exercise and PA for lifestyle. PA for exercise would be described as planned activity for a specific period of time, such as walking at a moderate to fast pace for 30 - 60 minutes, while lifestyle PA would be described as physical activity that is performed as part of daily living such as walking to work or taking the stairs instead of the elevator.²² While increasing lifestyle PA each day will not result in great amounts of weight loss, a combined effort of exercise and diet (energy restriction), resulting in a negative energy balance, have been shown to result in the greatest amount of weight loss.^{22,25}

Weight Loss Programs

There have been numerous studies addressing weight loss programs for those individuals who are obese. One study demonstrated that obese individuals experienced successful weight loss as a result of an increase in exercise, an altered diet, and the use of weight loss medications.¹² Successful weight loss was determined when obese individuals maintained the weight that was lost for a minimum of one year.¹² In this study, exercise was shown to be strongly associated with successful weight loss compared to diet and weight loss medications alone. This was not to say that diet was not important, but that diet alone was not sufficient in producing successful weight loss when compared to exercise. This research demonstrated that diet and exercise were useful tools in terms of losing weight, especially when used in conjunction with each other. Other weight loss

outcomes found with this self-reported study was that the participants lost more weight when they ate less fat, exercised more, and followed commercial weight loss diets.¹²

Research defines successful weight loss in obese individuals to be 10% or more of their initial body weight and weight maintenance for more than one year.^{12,26} Most weight loss studies were three to six months in length with a one year follow-up to determine the amount of weight loss and weight maintenance.^{12,26,27} Also, most studies included self-reported measures of physical activity.^{12,26,27} One study looked at the rate of initial weight loss to determine a safe and effective weight loss program. The study divided participants into three groups: a slow weight loss group, a moderate weight loss group, and a fast weight loss group.²⁶ The slow group consisted of weight loss equal to or less than 0.5 pounds per week, the moderate group consisted of weight loss between 0.5-1.5 pounds per week, and the fast group consisted of weight loss more than or equal to 1.5 pounds per week. Statistically, the fast, moderate, and slow weight loss groups did not significantly differ from each other ($p < 0.05$) in terms of weight loss maintenance. Even though all three methods were effective in producing weight loss, the slow and moderate weight loss groups were found to be the safest in terms of overall health.²⁶

It has been found that long-term regular physical activity contributes to successful weight maintenance. Long-term physical activity over a 10 year period has been shown to limit the amount of weight regained that occurs with aging.²⁵ Specifically, it was demonstrated that increases in intensity, time, and the number of exercise sessions per week were related to less weight regain in individuals over 45 years of age.²⁵ In addition, these FITT principle results had a greater association with women over men,

and that obese individuals experienced greater changes when compared to normal weight counterparts.²⁵

Successful weight loss in obese individuals has also been reported when participants outlined their anticipated results and recorded daily physical activity levels and diet diaries. A behavioral weight loss program was used to research weekly fluctuations in self-monitoring, outcome expectancies, difficulties with eating, and exercise.²⁸ The study included 40 obese participants who completed a six-month behavioral weight loss program where body weight, outcome expectancies, and difficulties with eating and exercise were measured weekly. Exercise and food diaries were utilized for the participants to log their physical activity and caloric intake. The results of this study showed that participants lost more weight during weeks where they reported positive outcome expectancies (expected results based on several health behavior change models) compared to weeks where they reported negative outcome expectancies.²⁸ The weeks in which participants experienced greater exercise frequency and weight loss were those in which they were consistent with self-monitoring exercise in their physical activity diary; this frequency was almost twice as much weight lost as when they were not consistent with self-monitoring. At the end of the six-month behavioral weight loss program, the participants lost an average of 7.6 kg (7% decrease, $p < 0.05$), increased their cardiovascular fitness level by 17.6% using a submaximal graded exercise test before and after the program, increased their duration of exercise on the treadmill by 78 minutes per week, and decreased their self-reported caloric intake by 776 calories per day (32% decrease, $p < 0.05$).²⁸ In addition, reassuring the participants that

regular exercise may not show detectable weekly changes but will benefit the patients in the long-term, was used to help with increased positive outcome expectancies.

Anti-Gravity Exercise

Often times, obese individuals exhibit a resistance to exercise due to a combination of musculoskeletal and orthopedic limitations, especially while walking. Limitations are often in the form of increasing pain, swelling, and subsequent gait changes.^{1,29} There are some exercises that reduce the gravitational forces (anti-gravity) placed on the body while doing weight-bearing activities. Swimming, or even walking in a pool, is one such anti-gravity activity that can reduce loads on the musculoskeletal system. It has been shown that walking in the pool can reduce lower extremity pain and allow obese individuals to sustain longer bouts of exercise.¹⁴ Unfortunately, exercising in a pool is considered a non-weight bearing activity and does not substantially contribute to bone density or structure.¹⁴

Conversely, walking on treadmills is often seen as a popular weight-bearing exercise device and positively affects bone mineral density and structure.¹⁴ Unfortunately, a traditional treadmill does not reduce the load placed on an individual's lower extremities, which could contribute to musculoskeletal issues or orthopedic limitations of obese individuals who use a treadmill to walk. To help minimize the load on the body while walking, several adaptations to treadmills have been made. In one study, an independent harness was constructed on a traditional treadmill for patients as way of decreasing loads in order to heal tissues, conserve energy, and reduce pain.¹⁵ Harness supported treadmills allowed individuals to rehabilitate injuries within their

functional capacity at lower energy cost, yet still produced significant cardiovascular conditioning.¹⁵

Partial body weight support using a suspended harness on a treadmill (LiteGait) is common in rehabilitation. One study investigated the use of a LiteGait system to determine the effects of suspended walking on gait patterns based on Froude number results.³⁰ The Froude number is a dimensionless ratio derived from a traditional walking model. The model uses an inverted pendulum to compare the contribution of forces from body inertia and gravity that demonstrates that the gravitational force is greater than the centrifugal forces in keeping the foot in contact with the ground.³⁰ Froude numbers are used in supported treadmill walking to determine the amount of unloading needed to reach an appropriate treadmill speed for rehabilitation. For example, a Froude number of 0.5 represents the change in gait from walking to running, whether the person is on the earth or on the moon.³⁰ The findings from this study indicated that gait patterns were affected by body weight unloading while walking in the LiteGait.³⁰

Further attempts at developing a treadmill device to reduce load, yet maintain weight-bearing benefits, were conducted by the National Aeronautics and Space Administration (NASA). Differential Air Pressure (DAP) was used to “weight” an individual harnessed into an enclosed treadmill.¹⁶ The lower body negative pressure (LBNP) created inside the walking chamber simulated the gravity-induced fluid shifts so that the astronauts could maintain cardiovascular function and bone density while in space.¹⁶

Based on the advances made by NASA on LBNP, the AlterG Company reversed the negative pressure to positive pressure (Lower Body Positive Pressure – LBPP) to

reduce weight in normal gravity situations found on Earth.¹⁷ The AlterG Anti-Gravity Treadmill was developed to accommodate LBPP (see Figure 2.1) and has been shown to increase proper gait mechanics, proper muscle firing and recruitment, as well as reducing heart rate in the rehabilitation setting.¹⁷ As part of a previously mentioned study regarding the LiteGait,³⁰ it was found that using a LBPP device was more closely aligned with unsupported gait mechanics, compared to the LiteGait. The research supported the use of LBPP device (AlterG Anti-Gravity Treadmill), not only for rehabilitative events, but also for individuals in a weight loss program. In addition, the AlterG Anti-Gravity Treadmill has allowed obese individuals to walk at lower percentages of their body weight by using LBPP to decrease the incidence of musculoskeletal pain and gait abnormalities that are typically seen in obese individuals.¹⁷

Further research has studied the effects of LBPP and the use of the AlterG Anti-Gravity Treadmill. One researcher looked at the changes in velocity and amount of weight support on ground reaction forces (GRFs) using the AlterG Anti-Gravity Treadmill and found that by changing the velocity and the amount of weight support, cardiovascular fitness levels could be maintained.³¹ This study consisted of 17 trials over two experimental sessions in a university research laboratory. The participants completed nine trials during session one and eight trials during session two with each session being seven minutes in length.³¹ Based on those findings, the AlterG Anti-Gravity Treadmill was found to be a beneficial exercise device for those individuals who had orthopedic limitations or excess body weight.³¹

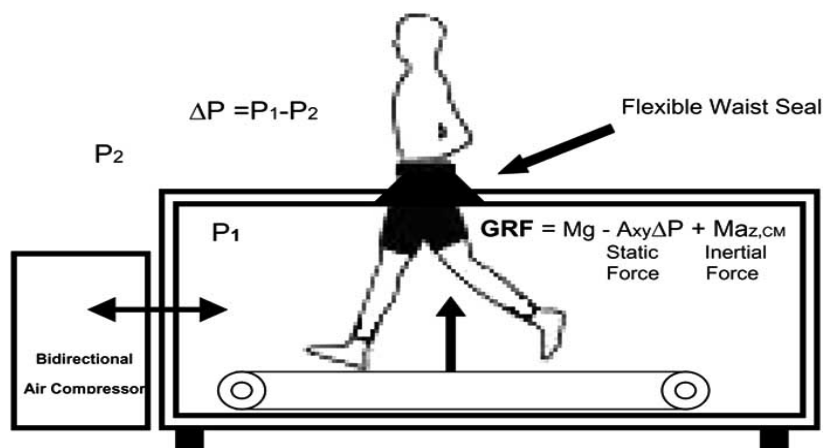


Figure 2.1 Illustration of LBPP in AlterG Anti-Gravity Treadmill³²

Another study looked at the effects of a LBPP device to produce weight loss in women.³³ The authors compared four groups of 20 women, which consisted of a traditional physical activity group (C), a diet only group (D), a diet and exercise group (DE), and a diet, exercise, and LBPP group (DEP) over a period of 12-weeks. The protocol for the two exercise groups was endurance-based training with 30 minutes of cycling at 50% of the participants $\dot{V}O_{2max}$, three times a week. A HypoxiS 120 LBPP device (comparable to a bicycle ergometer) was used for the DEP group. HypoxiS 120 training was also utilized in the DE group without the lower body pressure activated. Diets and exercises were constant throughout the appropriate groups. The data collected during the intervention were heart rate (Polar heart rate monitor), body weight, waist circumference, and resting metabolic rate (RMR). Indirect calorimetry was used to measure RMR, which was used to determine the participants' energy requirements and to calculate a negative energy balance. The DEP group lost 16.1% total body fat, the exercise and diet group lost 13.5% total body fat, the diet only group lost 7.8% total body fat, and the control group lost 1.5% total body fat across the 12-week intervention.³³ It was concluded that while the diet and exercise groups, as well as the LBPP groups,

produced significant weight loss, the LBPP showed the most significant weight loss (16.1%) because the LBPP is thought to increase the mobilization of extracellular water.³³ Extracellular water consists of interstitial fluid and plasma found outside of the cells and produces an unwanted cosmetic appearance in the form of cellulite, especially for women.³³ The LBPP also showed an increase in peripheral blood flow, which the authors speculated could benefit individuals with circulatory disorders, wound healing, or lymphedema.³³

There have been case studies researching the effectiveness of the AlterG Anti-Gravity Treadmill on various post-operative and lower extremity injuries such as ACL reconstruction, stress fractures, and joint replacements. One case study used the AlterG Anti-Gravity treadmill to determine the effects of a 14-week walking program with a morbidly obese individual.³⁴ The participant walked on the treadmill three times per week, and exercise intensity was kept between 40-60% of the participant's heart rate reserve. Initially, the exercise sessions included a five minute warm-up and cool-down and 10 minutes of walking. Duration increased to 65 minutes by the end of the study and was based on the participant's exercise tolerance and response. The researchers found that the walking program improved the participant's physical activity and exercise tolerance levels, but was insufficient to produce significant weight loss.³⁴ It was suggested that if the participant's exercise tolerance improved and the amount of LBPP was reduced, that more weight loss would have resulted. More research is still needed in looking at exercise-induced weight loss programs with the AlterG Anti-Gravity Treadmill for obese individuals.

Conclusion

In conclusion, it is clearly evident that exercise plays a critical role in weight loss and successful weight maintenance. Long-term physical activity has been shown to be the best source for weight change and weight maintenance. The use of LBPP treadmills have been shown to increase proper gait mechanics, proper muscle firing and recruitment in the lower extremities, as well as reducing heart rate in the rehabilitation setting. LBPP has also been found to be effective in maintaining cardiovascular fitness benefits while training in the device. Finally, the AlterG Anti-gravity treadmill appears to be a promising device to use by obese individuals who may benefit from decreased exercise loads as part of an exercise walking program.

CHAPTER THREE: METHODS AND PROCEDURES

This chapter will describe the participants and volunteer process for this study, along with the methods and procedures used in data collection. Finally, an explanation of data analyses will be provided.

Participants

Initially, 17 individuals volunteered to participate in the 18-week study. At the conclusion of the study, 15 volunteers (3 males; 12 females), ranging in age from 18-55 years (Mean \pm SD; 41.29 years \pm 7.82 years), completed the intervention and assessment periods for the data analysis. Participants were randomly assigned to the AlterG Anti-Gravity Treadmill group (AlterG; n = 6) and the traditional treadmill group (TT; n = 9).

Recruitment

Prior to beginning the study, the weight loss protocol underwent review and approval from the Boise State University Institutional Review Board (IRB) (see Appendix A). Upon approval, participants were recruited from the following programs and locations: Boise State University Kinesiology Department and Student Recreation Center, Boise YMCA centers, Boise Axiom Fitness clubs, Boise Engage Wellness clubs, and St. Luke's Wellness Program. Phone calls, emails, flyers, and word of mouth were used to advertise the need for participants at these various locations (see Appendix B).

Randomization

Participants first contacted the researcher if they were interested in enrolling in the study. Based on that contact, each volunteer was assigned an ID number, and was placed within a randomized treadmill grouping list generated using SPSS 21.0 where each ID corresponded to a random grouping number 1 (= AlterG Anti-Gravity Treadmill Group [AlterG]) or 2 (= Traditional Treadmill Group [TT]). For example, if a volunteer's ID number was six and the corresponding grouping number was two, then this volunteer would be assigned to the TT group. This process continued until the researcher received no further volunteer contacts.

Each participant was then scheduled for an orientation visit, which lasted approximately 2 hours. If the participant was excluded from the study based on the orientation visit, their name was removed off the randomized grouping list, and the next volunteer participant to contact the researcher was placed in the open slot. This process was continued until the researcher met with all of the participants who initially expressed interest in the study.

Orientation Visit

During the orientation visit, each participant was asked to complete the Informed Consent Form (see Appendix C) after the study protocol and procedures were discussed and any/all questions were answered. As part of the informed consent, participants were assured that they would have individual exercise sessions and would not be aware of other participants in the study. Individual status and progress during the training program would only be discussed with the participant and the lead researcher involved in the

study. All of the participant data would be entered into the computer and recorded using an ID code to ensure confidentiality

During the orientation visit, participants completed the Health History Questionnaire¹ to determine medical history such as, diseases, smoking history, medications, and allergies (see Appendix D). Based on the questionnaire results, participant risk was stratified as low, moderate, or high risk following ACSM's guidelines for pre-participation health screening and risk stratification.¹ Participants were excluded if they were of high risk in the risk stratification per ACSM guidelines.^{1,22}

- Low Risk: Asymptomatic men and women who have ≤ 1 CVD risk factor.
- Moderate Risk: Asymptomatic men and women who have ≥ 2 risk factors.
- High Risk: Individuals who have known cardiovascular, pulmonary, metabolic disease, or one of more signs and symptoms.

Those participants who were of low or moderate risk were then furthered asked to complete a Numeric Pain Scale (NPS) form for lower extremity pain (see Appendix E) and were measured for height and weight to determine BMI, along with skin fold and body circumference measurements.

Equipment and Measurements

Two treadmills were used during this study: (1) the AlterG Anti-Gravity Treadmill (model P200, AlterG, Inc. Fremont, CA), and (2) the Woodway Treadmill (model Desmo Hp, Woodway USA, Inc. Waukesha, WI). The Woodway treadmill is a traditional treadmill common to many fitness facilities. The AlterG Anti-Gravity Treadmill requires all users to calibrate the treadmill prior to use. Each time the AlterG

treadmill was used, it was calibrated for that specific participant. The Woodway treadmill was calibrated per the manufacturer settings and was not changed throughout the duration of the weight loss intervention. Both of the treadmills were located in the Human Performance Laboratory at Boise State University.

Several formative and summative measurements were collected and recorded as part of this research. The following measurements were taken at baseline, during the study, and at the conclusion: body weight, skinfold, waist-to-hip ratio, calf circumference, heart rate, blood pressure, Rating of Perceived Exertion (RPE), Numeric Pain Scale (NPS), and steps walked per day. The participant's body weight was measured at baseline and at week 6, 12, and 18 with the use of a digital Tanita scale (model BWB 800, Tanita Corporation, Tokyo, Japan). The participant's weight was also monitored before each exercise session to follow the safe exercise weight loss guidelines as presented by the ACSM.¹

Skin fold measurements were collected at baseline as well as week 6, 12, and 18. Body fat percentage was calculated using the Jackson-Pollock 7-site skinfold protocol, which includes chest, axilla, triceps, subscapular, abdominal, suprailiac, and thigh sites.¹ The lead researcher took all measurements at all points of the study to ensure reliability.

A heart rate monitor (model FT1, Polar Electro Oy, Oulu, Finland) was used during treadmill walking to monitor exercise intensity and target heart rate training zones, per the guidelines established in the weight loss protocol. Blood pressure, using a manual stethoscope and blood pressure cuff (Prospyg Aneroid Sphygmomanometer, ADC, Hauppauge, New York), was measured during and after each exercise session to ensure an appropriate exercise and recovery response.¹

Along with monitoring the target heart rate training zone, the RPE, using the modified Borg 1-10 scale, where 1 represents no work and 10 represents working as hard as possible, was used to indicate subjective perception of exercise intensity.¹⁹ The RPE scale was shown to the participants once they reached steady state of the walking protocol during each exercise session, and their response was recorded. An appropriate RPE was maintained for each training phase of the weight loss protocol.

To monitor lower body pain, the NPS was used to describe the level of pain in the lower extremities that the participants were experiencing while walking on the treadmills.¹⁸ The NPS is a numbered scale labeled from 0-10, with zero being no pain and 10 the most intense pain imaginable. The participants verbally reported what number best represented the level of pain they were experiencing. This pain scale was recorded at the beginning of the session, before and after each exercise session, and at the end of the session. The NPS has been proven to be a valid and reliable scale to assess pain.¹⁸

To monitor physical activity (PA) level outside of the exercise sessions, DigiWalker pedometers (SW200, Yamax, Japan) were used to calculate overall step counts per week. Other than removing the pedometer during treadmill walking sessions, participants were asked to wear the pedometer every day of the week, from the time they woke up to the time that they went to bed. The pedometer was placed on the mid-axillary line of their waistband. Participants were then asked to walk 10 steps to confirm the accuracy of the pedometer steps. If the pedometer was not within one step of the actual steps, the pedometer was moved to the back of the waistband and the test was completed again. Some of the participants, due to excessive waist circumference, moved the pedometer to the middle of their lower back to maintain a more vertical position.³⁵

Participants were told not to wear the pedometer in any water activity as the pedometers were not waterproof. The participants kept a log of their steps each day and turned in their log once a week to the lead researcher for documentation. Finally, participants were reminded to maintain their normal daily routines throughout the study. For a summary schedule of all collected measurements, see Table 3.1.

Table 3.1 Summary of Measurements

| Measurements | Baseline | Before Exercise | During Exercise | After Exercise | Week 6 and 12 | Post |
|---------------------------|-----------------|----------------------------|----------------------------|---------------------------|--------------------------|-------------|
| Body Weight | Yes | Yes | | | Yes | Yes |
| BMI | Yes | | | | Yes | Yes |
| Skinfold | Yes | | | | Yes | Yes |
| Heart Rate | Yes | Yes | Yes | Yes | Yes | Yes |
| Blood Pressure | Yes | Yes | Yes | Yes | Yes | Yes |
| RPE | Yes | Yes | Yes | Yes | Yes | Yes |
| NPS | Yes | Yes | Yes | Yes | Yes | Yes |
| Pedometer | | Yes | | | Yes | |

Weight Loss Protocol

Exercise Sessions

The weight loss protocol was an 18-week walking intervention wherein three exercise sessions were completed per week. The intervention was broken down into three

6-week phases: immediate, intermediate, and advanced. Target heart rates and training zones were calculated using the participant's age predicted maximum heart rate, as established by the ACSM.¹ The training zones, 20-85% of age predicted heart rate maximum, were determined by the guidelines listed in the weight loss protocol. The participants wore a heart rate monitor to ensure proper training intensity within each phase of the weight loss protocol.^{1,22} The following outlines the protocol followed for each phase of the study.

Phase 1: Immediate 1-6 Weeks

Phase Goals

- Began weight loss program
- Monitored heart rate, blood pressure and Rating of Perceived of Exertion (RPE) throughout
- Aimed for 30 minutes of physical activity 3 days a week, either continuously or at regular intervals of at least 10 minutes duration as tolerated by the participant
- Physical activity began at a mild to moderate intensity, target heart rate = 20-40% of age predicted heart rate maximum; calculated by: $(206.9 - (0.67 \times \text{age})) \times 20$ and 40% respectively.¹ RPE should be low, 1-3 on a modified Borg scale of 1 – 10

AlterG Anti-Gravity Treadmill Exercise

Physical activity began at a mild-to-moderate intensity. The participant walked at 50-70% of their effective body weight (as adjusted on AlterG Anti-Gravity Treadmill) at 1.5-3.5 mph for 30 minutes. All participants began walking at 50% of their effective body

weight and were progressed individually based on fitness and comfort level. The AlterG Anti-Gravity Treadmill had the participant enclosed in a waist-high pressure chamber that inflated or deflated to reach the desired weighted percentage. Weight percentage was determined with the AlterG Anti-Gravity Treadmill by the pressure produced by the participant standing on a force plate under the belt of the treadmill and from that determined how much to inflate or deflate when the desired weighted percentage was selected. Once a comfortable walking speed had been established and heart rate was below the target zone, the treadmill incline was increased to bring the heart rate into the target zone. As the individual adapted, the training program was progressed each session to allow pain free physiological adaptations to continue by increasing one of the following: body weight, exercise intensity (speed and/or grade) by 1-5% as tolerated. When increasing exercise intensity, the participant's heart rate was kept in the target HR zone and an RPE range of 1-3.^{1,22}

Woodway Treadmill Exercise

Physical activity began at a mild-to-moderate intensity. The participant walked at 1.5-3.5 mph for 30 minutes. Once a comfortable walking speed had been established and heart rate was below the target zone, the treadmill incline was increased to bring the heart rate into the target zone. As the individual adapted, the training program was progressed each session to allow pain free physiological adaptations to continue by increasing one of the following: exercise intensity (speed and/or grade) by 1-5% as tolerated. When increasing exercise intensity, the participant's heart rate was kept in the target HR zone and an RPE range of 1-3.^{1,22}

Phase 2: Intermediate 6-12 weeks

Phase Goals

- Continued weight loss program
- Monitored heart rate, blood pressure and RPE as previously described
- Aimed for 45 minutes of physical activity 3 days a week, either continuously or at regular intervals of at least 10 minutes duration as tolerated by the participant
- Physical activity was at a moderate intensity, 40-60% of age predicted heart rate maximum; calculated by: $(206.9 - (0.67 \times \text{age})) \times 40$ and 60% respectively.¹ RPE was moderate, around 3-5

AlterG Anti-Gravity Treadmill Exercise

Physical activity was at a moderate intensity. The participant walked at 70-80% of their effective body weight for 45 minutes, as adjusted on the AlterG Anti-Gravity Treadmill. The participant achieved target heart rate by walking at 2.5-4.0 mph. Once a comfortable walking speed had been established and heart rate was below the target zone, the treadmill incline was increased to bring the heart rate into the target zone. When increasing exercise intensity, the participant's heart rate and RPE was kept in the target zone as previously discussed.^{1,22}

Woodway Treadmill Exercise

Physical activity was at a moderate intensity. The participant achieved target heart rate by walking at 2.5-4.0 mph for 45 minutes. Once a comfortable walking speed had been established and heart rate was below the target zone, the treadmill incline was increased to bring the heart rate into the target zone. When increasing exercise intensity,

the participant's heart rate and RPE was kept in the target zone as previously discussed.^{1,22}

Phase 3: Advanced 12-18 Weeks

Phase Goals

- Continued weight loss program
- Monitored and teach heart rate, blood pressure and RPE as previously described
- Aimed for 60 minutes of physical activity 3 days a week, either continuously or at regular intervals of at least 10 minutes duration as tolerated by the participant
- Physical activity was at a moderate to vigorous intensity, 60-85% of age predicted heart rate maximum, calculated by: $(206.9 - (0.67 \times \text{age})) \times 60-85\%$ respectively.¹
RPE was moderate to slightly vigorous, around 5-7

AlterG Anti-Gravity Treadmill Exercise

Physical activity was at a moderate-to-vigorous intensity. The participant fast walked/light jogged at 80-95% of their effective body weight for 60 minutes, 4.0+ mph or by increasing the incline on the AlterG Anti-Gravity Treadmill to 3-5% as tolerated and adjusted on the AlterG Antigravity Treadmill. Once a comfortable walking speed had been established and heart rate was below the target zone, the AlterG Anti-Gravity Treadmill incline was increased to bring the heart rate into the target zone. When increasing exercise intensity, the participant's heart rate and RPE was kept in the target zone as previously discussed.^{1,22}

Woodway Treadmill Exercise

Physical activity was at a moderate-to-vigorous intensity. The participant fast walked/light jogged for 60 minutes, 4.0+ mph or by increasing the incline to 3-5% as tolerated and adjusted on the Woodway Treadmill. Once a comfortable walking speed had been established and heart rate was below the target zone, the incline was increased to bring the heart rate into the target zone. When increasing exercise intensity, the participant's heart rate and RPE was kept in the target zone as previously discussed.^{1,22}

Data Analysis

Weight, BMI, and body fat percentage from the beginning to the end of the intervention were analyzed to evaluate the success of the program. All collected data were logged into an Excel spreadsheet throughout the duration of the weight loss program. Data were analyzed using SPSS, version 21.0 (SPSS Inc., Chicago, IL). Descriptive statistics were carried out for body weight, BMI, body fat percentage, average steps per day, NPS scores, and compliance rates. Separate 2 (treadmill group) x 4 (time) repeated measures ANOVA, where group is the between subject independent variable and time is the within group variable, was conducted to determine whether statistical significant differences existed for the multiple dependent variables (e.g., weight, BMI, and body fat percentage) from beginning to end of the study. If significance was found, a Least Significant Difference (LSD) post-hoc test was used to determine which specific phases of the study were significant.

CHAPTER FOUR: RESULTS

Participants

Fifteen obese participants, aged 42.73 ± 7.03 years old with a BMI ≥ 30 kg/m², completed the walking program and were included in the final data analyses. Participants were randomly assigned to either the AlterG Anti-Gravity Treadmill group or Traditional Treadmill group (see Table 4.1).

Table 4.1 Description of Gender, Age, Height, and Weight

| Group | Age (years) | | Height (cm) | Weight (kg) |
|---------------------|-------------|------------------|--------------------|--------------------|
| | n | Mean \pm SD | Mean \pm SD | Mean \pm SD |
| AlterG Group | | | | |
| Males | 1 | 36.00 | 172.72 | 101.70 |
| Females | 5 | 43.20 ± 8.12 | 162.30 ± 9.91 | 91.22 ± 17.08 |
| Total | 6 | 42.00 ± 7.87 | 164.04 ± 9.18 | 92.97 ± 15.87 |
| TT Group | | | | |
| Males | 2 | 41.00 ± 8.49 | 187.33 ± 11.67 | 118.55 ± 10.11 |
| Females | 7 | 43.86 ± 6.96 | 166.01 ± 6.34 | 114.03 ± 21.62 |
| Total | 9 | 43.20 ± 6.85 | 170.75 ± 11.64 | 115.03 ± 19.17 |
| Total | 15 | 42.73 ± 7.03 | 168.06 ± 10.91 | 106.21 ± 20.62 |

Effects of the Walking Intervention

Weight

The average weight for all of the participants prior to the start of the weight loss intervention was $105.24 \text{ kg} \pm 19.66 \text{ kg}$ (Mean \pm SD). There was a statistically significant difference for weight between the AlterG and TT groups at baseline, $p = 0.024$. By the end of the weight loss intervention, the average weight for all of the participants was $102.92 \text{ kg} \pm 21.02 \text{ kg}$. For the AlterG group, the baseline average weight was $92.97 \text{ kg} \pm 15.87 \text{ kg}$ and the post average weight was $90.63 \text{ kg} \pm 13.47 \text{ kg}$. For the TT group, the baseline average weight was $115.03 \text{ kg} \pm 19.17 \text{ kg}$ and the post average weight was $113.44 \text{ kg} \pm 21.27 \text{ kg}$. The average amount of weight loss in kilograms for all participants was 2.2 kg, and the average percent change of weight loss in kilograms was 2.0%. The AlterG group lost an average of 2.3 kg (2.19%) compared to the TT group that lost an average of 2.1 kg (1.83%) (see Figure 4.1).

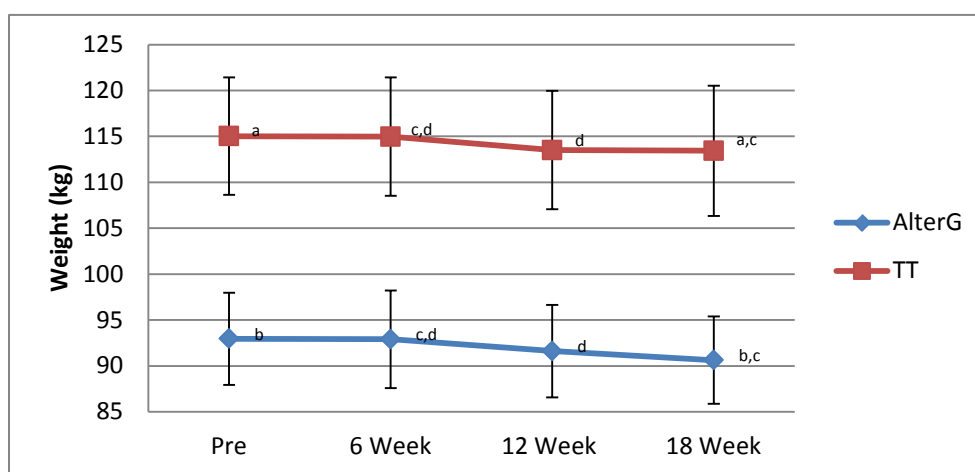


Figure 4.1 Body Weight (kg) for All Participants by Treadmill Group

Note. Same subscripts differ significantly among groups and weeks at $p < 0.05$.

^aAlterG Baseline and Post; ^bTT Baseline and Post; ^{c,d}Week difference

There was a significant difference between the two treadmill groups, $F_{(1, 11)} = 4.60$, $p = 0.055$, eta squared = 0.295, observed power = 0.499. The participants in the TT group always had a higher weight compared to the AlterG group. There was a significant difference among the three phases of the weight loss intervention, $F_{(1.35, 14.89)} = 5.59$, $p = 0.024$, eta squared = 0.337, observed power = 0.675. The participants at baseline and at week 6 of the weight loss intervention had a higher weight when compared to week 12 and week 18 of the weight loss intervention. A Least Significant Difference (LSD) post-hoc test revealed a significant weight difference between week 6 and week 12 ($p = 0.002$) and between week 6 and week 18 ($p = 0.016$). There was not a significant interaction between the two treadmill groups and the intervention phases on body weight, $F_{(1.35, 14.89)} = 0.11$, $p = 0.822$, eta squared = 0.010, observed power = 0.062. Both groups responded to the weight loss intervention similarly, and participant weight loss was similar between both the AlterG group and the TT group (see Table 4.2).

Body Mass Index

The average BMI for all of the participants prior to the start of the weight loss intervention was $37.09 \text{ kg/m}^2 \pm 5.42 \text{ kg/m}^2$. There was a significant difference found for BMI between the AlterG and TT groups at the beginning of the study, $p = 0.041$. At the end of the weight loss intervention, the average BMI for all of the participants was $36.06 \text{ kg/m}^2 \pm 5.34 \text{ kg/m}^2$. For the AlterG group, the baseline average BMI was $34.32 \text{ kg/m}^2 \pm 2.69 \text{ kg/m}^2$ and the post average BMI was $33.52 \text{ kg/m}^2 \pm 2.06 \text{ kg/m}^2$. For the TT group, baseline average BMI was $39.57 \text{ kg/m}^2 \pm 6.25 \text{ kg/m}^2$ and the post average BMI was $38.22 \text{ kg/m}^2 \pm 6.46 \text{ kg/m}^2$ (see Figure 4.2).

Table 4.2 Weight and Body Composition Averages by Treadmill Group

| Variable | Group | n | Baseline | Week 6 | Week 12 | Week-18 Post |
|-----------------------------|---------------|---|-----------------------|----------------------|---------------------|-----------------------|
| | | | Mean \pm SD | Mean \pm SD | Mean \pm SD | Mean \pm SD |
| Weight (kg) | AlterG | 6 | 92.97 \pm | 92.92 \pm | 91.62 \pm | 90.63 \pm |
| | | | 15.87 _a | 15.02 _{c,d} | 14.28 _d | 13.47 _{a,c} |
| | TT | 9 | 115.03 \pm | 114.98 \pm | 113.51 \pm | 113.44 \pm |
| | | | 19.17 _b | 19.31 _{c,d} | 19.36 _d | 21.27 _{b,c} |
| BMI (kg/m ²) | AlterG | 6 | 34.32 \pm | 34.33 \pm | 33.87 \pm | 33.52 \pm |
| | | | 2.69 _{a,c,d} | 2.42 _{e,f} | 2.29 _{c,e} | 2.06 _{a,d,f} |
| | TT | 9 | 39.57 \pm | 39.54 \pm | 39.01 \pm | 38.22 \pm |
| | | | 6.25 _{b,c,d} | 6.22 _{e,f} | 6.08 _{c,e} | 6.46 _{b,d,f} |
| BF (%) | AlterG | 6 | 36.64 \pm | 35.49 \pm | 34.38 \pm | 32.79 \pm |
| | | | 3.61 _{a,c} | 3.82 _c | 4.54 _c | 4.55 _{a,c} |
| | TT | 9 | 36.57 \pm | 35.62 \pm | 34.70 \pm | 33.44 \pm |
| | | | 4.72 _{b,c} | 4.89 _c | 4.91 _c | 5.77 _{b,c} |

Note. Means \pm SD with same subscripts differ significantly among groups and weeks at $p < 0.05$.

^aAlterG Baseline and Post

^bTT Baseline and Post

^{c,d,e,f} Week difference

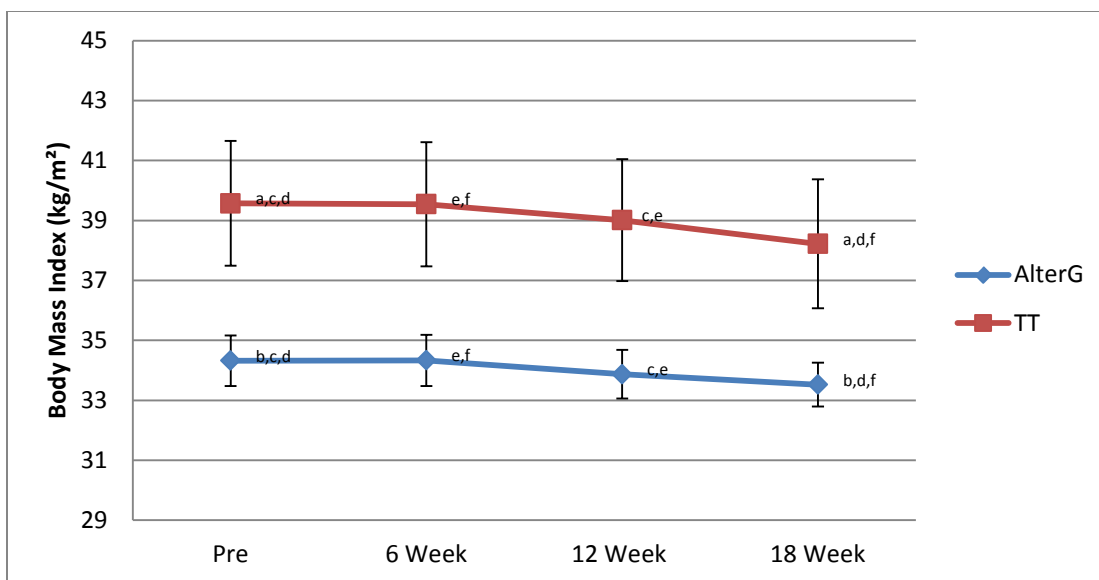


Figure 4.2 Body Mass Index (kg/m²) for All Participants by Treadmill Group

Note. Means \pm SD with same subscripts differ significantly among groups and weeks at $p < 0.05$.

^aAlterG Baseline and Post

^bTT Baseline and Post

^{c,d,e,f}Week difference

There was no statistical difference found between the two treadmill groups, $F_{(1, 11)} = 2.48$, $p = 0.144$, eta squared = 0.184, observed power = 0.301. There was a significant difference among the three phases of the weight loss intervention, $F_{(1.34, 14.73)} = 5.90$, $p = 0.021$, eta squared = 0.349, observed power = 0.695. The participants at baseline and at week 6 of the intervention had a higher BMI when compared to week 12 and 18 of the intervention. A LSD post-hoc test revealed a significant difference between baseline and week 12 ($p = 0.044$), between baseline and week 18 ($p = 0.043$), between week 6 and week 12 ($p = 0.003$), and between week 6 and week 18 ($p = 0.017$). There was not a significant interaction between the two treadmill groups and intervention phases on BMI, $F_{(1.34, 14.73)} = 0.13$, $p = 0.793$, eta squared = 0.012, observed power =

0.065. Both groups responded to the weight loss intervention similarly and participant BMI loss was similar between both the AlterG group and the TT group (see Table 4.2).

Body Fat Percentage

The average body fat percentage (BF) for all of the participants at the start of the study was $36.49\% \pm 4.09\%$. There was no statistical difference for BF between the AlterG and TT groups, $p = 0.932$. By the end of weight loss intervention, the average BF was $33.14\% \pm 5.04\%$. For the AlterG group, the baseline average BF was $36.64\% \pm 3.61\%$ and the post average BF was $32.79\% \pm 4.55\%$. For the TT group, baseline average was $36.57\% \pm 4.72\%$ and the post average was $33.44\% \pm 5.77\%$ (see Figure 4.3).

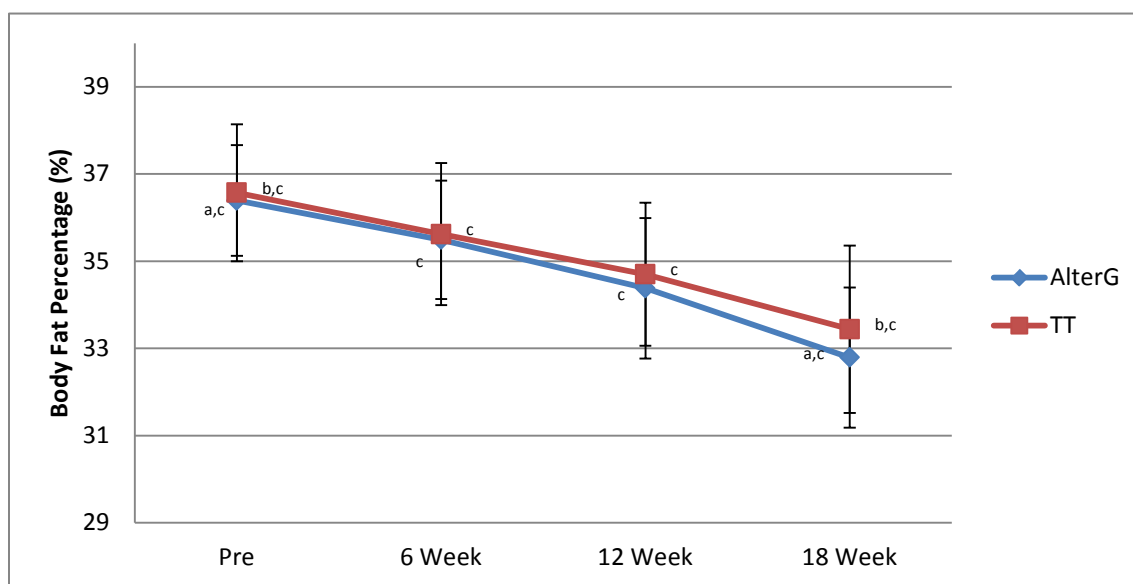


Figure 4.3 Body Fat Percentages (%) for All Participants by Treadmill Group

Note. Means \pm SD with same subscripts differ significantly among groups and weeks at $p < 0.05$.

^aAlterG Baseline and Post

^bTT Baseline and Post

^cWeek difference

There was no statistical difference in BF percent between the two treadmill groups, $F_{(1, 11)} = 0.01$, $p = 0.920$, eta squared = 0.001, observed power = 0.51. There was a significant difference found among the three phases of the weight loss intervention, $F_{(1.34, 14.69)} = 67.05$, $p < 0.0005$, eta squared = 0.859, observed power = 1.000. The participants at baseline and at week 6 of the intervention had a higher body fat percentage when compared to week 12 and week 18 of the intervention. A LSD post-hoc test revealed a significant BF percent difference between baseline and week 6 ($p = 0.001$). Significance differences among all other phases of the weight loss intervention were revealed ($p < 0.05$). There was not a significant interaction between the two treadmill groups and the intervention phases on BF percent, $F_{(1.34, 14.69)} = 0.47$, $p = 0.560$, eta squared = 0.041, observed power = 0.103. Both groups responded to the weight loss intervention similarly and body fat percentage decreased similarly between the AlterG group and the TT group (see Table 4.2).

Physical Activity Levels

The average steps per day for the AlterG group was 7664.71 ± 1983.71 steps, while the TT group reported an average of 6077.85 ± 2323.46 steps. There was no significant difference between the two treadmill groups for the average number of steps walked per day, $F_{(1, 6)} = 0.50$, $p = 0.506$, eta squared = 0.077, observed power = 0.092. There was no significant difference found among the three phases of the intervention, $F_{(1.14, 6.84)} = 1.21$, $p = 0.319$, eta squared = 0.167, observed power = 0.163. Lastly, there was not a significant interaction between the two treadmill groups, $F_{(1.14, 6.84)} = 0.61$, $p = 0.481$, eta squared = 0.093, observed power = 0.106 (see Table 4.3). Daily physical

activity patterns remained consistent and were not a factor in the weight loss that occurred during the walking program.

Table 4.3 Average Step Count Level by Treadmill Group

| Variable | Group | n | Week 6 | Week 12 | Week 18-Post | Total |
|-------------|---------------|---|---------------|---------------|---------------|---------------|
| | | | Mean \pm | Mean \pm | Mean \pm | Mean \pm |
| | | | SD | SD | SD | SD |
| PA Level | AlterG | 6 | 6821.07 \pm | 8270.20 \pm | 7189.65 \pm | 7664.71 \pm |
| (steps/day) | | | 1873.62 | 2440.74 | 2005.29 | 1983.71 |
| PA Level | TT | 9 | 6889.71 \pm | 6519.19 \pm | 5529.45 \pm | 6077.85 \pm |
| (steps/day) | | | 3237.19 | 2081.47 | 2339.89 | 2323.46 |

* $p < 0.05$

Numeric Pain Scores

During each exercise session, the participants were asked to rate their level of lower extremity pain using the 10-point Numeric Pain Scale (NPS). Prior the start of the weight loss intervention, the average NPS value for all of the participants was 0.50 ± 1.00 . There was a statistically significant difference for NPS between the AlterG and TT groups at baseline, $p = 0.048$. The TT group had higher NPS scores at the beginning of the weight loss intervention, 0.94 ± 1.24 , compared to the AlterG group, 0.00 ± 0.00 . By the end of the weight loss intervention, the average NPS value for all of the participants was 0.75 ± 1.23 . For the AlterG group, the average NPS value at baseline was 0.00 ± 0.00 and the ending average NPS value was 0.67 ± 1.21 . For the TT group, the average NPS value at baseline was 0.94 ± 1.24 and the post average value was 0.83 ± 1.33 .

Exercise Adherence

There were 18 sessions per each 6-week phase of the study for 54 sessions. Based on exercise adherence, the AlterG group maintained at least a 79% (43 sessions) compliance rate over the course of the study, while the TT group demonstrated a 69% (37 sessions) attendance rate (see Table 4.4). No significant differences were found between the two treadmill groups for total adherence rates ($p = 0.25$).

Table 4.4 **Number of Sessions Completed and Percentages by Treadmill Group**

| Group | Week 6 | | Week 12 | | Week 18- | | Total | |
|---------------|---------------|---------------------|----------------|---------------------|-----------------|--------------------------|--------------|---------------------|
| | n | Sessions (%) | n | Sessions (%) | n | Post Sessions (%) | n | Sessions (%) |
| AlterG | 6 | 15 (83%) | 6 | 14 (77%) | 6 | 14 (77%) | 6 | 43 (79%) |
| TT | 9 | 15 (81%) | 9 | 13 (72%) | 7 | 13 (72%) | 9 | 37 (69%) |
| Total | 15 | | 15 | | 13 | | 15 | |

* $p < 0.05$

CHAPTER FIVE: DISCUSSION AND CONCLUSION

Discussion

The purpose of this study was to determine if the AlterG Anti-Gravity Treadmill was an effective method for increasing physical activity in a weight loss program when compared to a traditional treadmill. Four main hypotheses were studied. It was hypothesized that (1) regular use of the AlterG Anti-Gravity Treadmill would result in statistically significant exercise-induced weight loss in obese individuals, (2) the traditional treadmill group (TT) would lose more weight than the AlterG Anti-Gravity Treadmill (AlterG) group at the conclusion of the intervention, (3) the AlterG group would have lower Numeric Pain Scores (NPS) while walking than those walking on a traditional treadmill, and (4) the AlterG group would have higher compliance rates during the intervention than the TT group.

Hypothesis 1

The first hypothesis stated that regular use of the AlterG Anti-Gravity Treadmill would cause statistically significant exercise-induced weight loss. The current study supported this hypothesis. Weight loss, BMI, and body fat percentage changes on the AlterG were statistically significant from baseline to the end of the intervention. On average, those individuals following the AlterG Anti-Gravity walking program lost 2.33 kg over the course of the 18-week program.

A separate study using a LBPP device in a weight-loss intervention found similar results to the current study. Participants using the LBPP device produced an overall weight loss of 4.75 kg (16.1%).³³ Although participants in the current study reported significant weight loss, the amount of loss (2.0%) was less than reported by the previous study. Similar comparisons between the two studies were also found for total body fat. The LBPP device group in the above study lost 16.1% total body fat over a period of 12-week intervention while participants in the current study only reduced body fat percentages by 2.0 percent over the course of 18 weeks. This difference could be because the other study used higher exercise intensities during the intervention. The participants in that study exercised at 50% $\dot{V}O_{2max}$ for 30 minutes three days per week, whereas participants in the current study exercise at percentages of maximum heart rates for 30-60 minutes 3 days per week. $\dot{V}O_{2max}$ is the maximum volume of oxygen that the body can consume during exercise and is more accurate than using estimated maximum heart rates.¹ Using estimated maximum heart rates can under or overestimate the individual's true training zone. The current study had low Phase 1 intensity levels, which could have contributed to the lower overall weight and percent body fat loss at the end of the intervention.

Weight-loss results of the current study were in disagreement with a previous study that used the AlterG Anti-Gravity treadmill to determine the effects of a 14-week walking program with one morbidly obese individual.³⁴ While the participant walked on the treadmill three times per week, and exercise intensity was kept between 40-60% of the participant's heart rate reserve, the researchers found that the walking program was insufficient to produce significant weight loss.³⁴ The difference between the two studies

may be explained by the duration and intensity levels of the walking program design. Participants in the current study increased their intensity levels to 60-85% of maximum heart rate during the last 6 weeks of the study, whereas the case study maintained an intensity level of 40-60%. In addition, the current study extended the walking program by four additional weeks, which could have accounted for the difference in significant weight loss. While the ASCM recognizes that longer intensity levels at a moderate level (40 – 60% HRR) may aid in weight loss with obese individuals,¹ the extended walking sessions of the current study may have played a significant role.

Hypothesis 2

It was hypothesized that the traditional treadmill (TT) group would lose more weight than the AlterG Anti-Gravity Treadmill (AlterG) group; however, results from the current study did not support this hypothesis. In addition, the results of this study were not supported by a previous research study that reported that participants using the LBPP device produced the most amount of weight loss (4.75 kg; 16.1%) when compared to a traditional treadmill group, a diet only group, and a diet and traditional exercise group.³³ The researchers hypothesized that the LBPP group outperformed the other groups due to the influence of LBPP and the associated increase in blood flow.³³

In the current study, both groups lost a significant amount of weight. It was initially thought that the TT group would lose more weight than the AlterG group because the traditional treadmill uses full weight-bearing forces while walking, which could result in additional energy expenditure. Perhaps the weight loss protocol was too easy for the TT group and the intensity and duration was not enough to demonstrate a difference in post-intervention weight loss scores. While not significant, the AlterG group

did demonstrate a higher overall weight loss compared to those walking on the regular treadmill. Although the reasons for this difference is unclear, those who used the AlterG could have lost more weight because the participants had to learn to walk in the new treadmill, requiring them to expend more energy to help maintain balance or increase arm movements due to walking in the enclosed space.

Hypothesis 3

The third hypothesis was that the AlterG group would have lower Numeric Pain Scores (NPS) than the TT group. This hypothesis was not supported by the results. Research has looked at the effects of the AlterG Anti-Gravity Treadmill and other LBPP devices on reduced GRFs. The LBPP reduces those forces by 49-72%, meaning that individuals using those devices could preserve gait mechanics, even when limited by orthopedic issues.³¹ LBPP has been used in several rehabilitation studies and have been proven effective in helping post-operative patients reduce their pain and regain muscle strength due to muscle atrophy caused by initial inactivity.³¹

The participants who were recruited for this study did not necessarily have chronic lower extremity pain to begin with. It is also plausible that the walking protocol for both the AlterG and traditional treadmill was not rigorous enough to create an inflammatory response and pain in the lower extremities. It is unclear whether increasing higher intensities earlier in the walking program would have resulted in higher levels of perceived pain, especially for those walking on the traditional treadmill.

There was one anomaly that occurred during the second phase of the program, which demonstrated an increase of perceived pain in the AlterG Anti-Gravity Treadmill group. Three of the participants reported an injury sustained outside of this study. For

example, one male AlterG group participant competed in a race with his daughter and twisted his knee while a female TT group participant fell off the sidewalk and broke a rib and fractured her elbow. Finally, the third injury occurred when another female TT group participant fell and sustained a third degree ankle sprain, which prevented her from walking on the treadmill. The two female participants did not participate in Phase three of the weight loss intervention. This could have affected the NPS results as well because these two participants did not report their Phase three NPS scores. These independent injuries could explain why the AlterG group experienced more pain during their walking sessions in the second phase of the weight loss program.

Hypothesis 4

The fourth hypothesis of this study suggested that the AlterG group would have higher compliance rates during the intervention than the TT group. While the AlterG group did attend more exercise sessions (79%) than the TT group (69%), the difference was not significant. Nevertheless, the six additional days of participation by the AlterG group may have been due to the uniqueness of the anti-gravity treadmill. Participants in this group knew that they would be able to walk/jog at faster speeds and greater elevations with a lower heart rate due to the reduced body weight effect of the special treadmill. The added anticipation of walking in a special device might have added a positive psychological component to the exercise sessions, motivating participants to continue with the walking program. There is evidence to suggest that positive and negative psychological effects of weight loss can be dependent on a participant's perceived success of the program.²¹ The AlterG participants in this study may have felt that they were experiencing positive results or that they were improving their

cardiovascular level faster due to walking in the device, which could have contributed to their higher participation rates. As such, it is important to encourage the participant's perceived success to help maintain program adherence to the weight loss program.^{1,29}

One final action may have contributed to the moderate participation rate (73%) for both groups. Participants in the current study were weighed before every exercise session. Research has suggested that daily weighing is an important aspect of healthy dietary and exercise behaviors when associated with weight loss or weight maintenance.³⁶ The action of recording weight in this study may have contributed to exercise adherence with both groups.

Program adherence is always a concern in weight loss intervention studies.^{1,22} It is essential to note that two participants dropped out of the study at the beginning of Phase 3 due to injuries they sustained outside the study. One participant fell off the sidewalk, broke a rib, and fractured her elbow. The other participant fell and sustained a third degree ankle sprain, which prevented her from walking on the treadmill. Both of the participants did return for their final testing at the end of the study. Program adherence during Phase 3 also became more challenging for others in the study; excuses became more prevalent. Some of the excuses were "I am too tired," "I don't have time to exercise for 60 minutes," or "I just don't feel like it." Encouragement and positive motivation by the researcher during Phase 3 helped participants complete the study.

Other Findings

Participants in this study were provided a pedometer to wear during the 18-week walking program. While no home exercise program was given to the participants, they were asked to monitor and log total number of steps each day. In addition, participants

were not informed of recommended step counts or instructed to improve upon daily counts. Based on pedometer steps, it was found that daily physical activity remained consistent throughout the duration of the study, with no significant step count differences occurring within and between groups. In other words, participants in this study maintained a regular daily routine of physical activity throughout the study. The AlterG group reported an overall increase of only 844 steps, while participants in the TT group reduced their daily steps by 812 by the end of the study. No baseline pedometer steps were taken prior to the start of the study. Despite the lack of baseline step counts, it could be inferred either that step count values prior to the start of the intervention were similar or that both treadmill groups responded with daily physical activity to the same degree. Overall, this outcome demonstrated that daily physical activity was not a factor in the weight loss results. Therefore, the weight loss gains from this study may be largely attributed to the 18-week walking program utilizing the AlterG Anti-Gravity Treadmill and the traditional treadmill.

The step count logs from this study were a bit surprising. Pedometers can be considered a type of motivation device due to the capability of viewing step counts throughout the day. Viewing daily steps can motivate individuals to maintain or improve steps over time.³⁵ In addition, the act of logging and charting step counts at the end of each day is a form of self-regulation that has been shown to enhance motivation and exercise adherence.³⁵ However, it appeared the participants in this study did not view the pedometers as anything other than a required task of the study, as opposed to using the pedometers as a motivational tool to increase daily steps and physical activity levels.

Limitations

This study consisted of a small sample size of 15 participants. However, other studies using LBPP devices have also reported a small sample size. One study reported using 10 participants over two experimental lab sessions,³¹ while another study reported 12 participants in a one-time lab testing.³⁰

Despite the small number of participants, the results of the current study are similar to those found in other weight loss studies not using LBPP devices. One study used a sample size of 40 participants in a six month behavioral weight loss program and found similar reductions in body weight as compared to this study.²⁸ A second study analyzed 15,000 participants who self-reported physical activity levels over a 10 year period and found that increased intensity and frequency resulted in greater amounts of weight loss, specifically with jogging, aerobics, and cycling.²⁵

This study was also limited in time available for walking sessions each week and the length of time of the study. There was only one technician available to work with participants each week. As a result, walking sessions were limited to three days per week over the course of 18 weeks. A higher frequency of walking sessions per week and a longer intervention could have possibly shown higher weight loss results. This study was 18 weeks in duration, and most of the research support that long-term weight loss programs of six months or more are beneficial in producing significant reductions in weight.

This study did not control for any dietary factors. Dietary logs were not collected to determine any changes in diet across the study. As such, the weight loss experienced

by participants in this study may not have been exclusively attributed to effectiveness of the walking program using the AlterG Anti-Gravity Treadmill and traditional treadmill.

A final limitation of this study was in regards to program adherence. Participants in this study were not consistent in completing weekly walking sessions during the full 18-week weight loss intervention. The participants had a difficult time adapting to a new exercise program and exercising three days a week. Most of the participants were not currently exercising, so this weight loss intervention was a significant lifestyle change for them. The training days that were missed during the study could have affected the overall amount of weight loss seen with the participants. If the participants had consistently attended more sessions, their overall energy expenditure could have resulted in larger weight losses at the conclusion of the study. In addition, the lack of participation incentives may have contributed to the inconsistent participation rates.

Future Applications

Although significant weight loss was reported during the 18-week walking program, the overall loss was less than reported in other studies. Future research should explore a more aggressive weight loss protocol when using the AlterG Anti-Gravity Treadmill and traditional treadmill. A more progressive training schedule may produce larger weight-loss results. Phase 1 of the weight loss protocol was very light in intensity and would have benefited from a more moderate workload. As such, it is recommended to use the intensity training level of Phase 2 (40-60% HRR) as part of the initial Phase 1 workload protocol.

It is also recommended to increase the frequency of training sessions to maximize weight loss potential. The ACSM recommends between 250–300 minutes of physical

activity each week for obese individuals. Participants in phase one of this study were completing 90 minutes of walking each week and 135 minutes during phase two. By phase three, the participants were completing 180 minutes of walking for six weeks. At no point in this study did the participants complete ACSM's recommendation of 250-300 minutes of physical activity each week. If the training schedule for the AlterG and traditional treadmill were to increase by one additional day (e.g., 4 days/week), and walking sessions were extended, participants would come closer to the recommended levels of physical activity. Several exercise intervention studies also reported that extended programs resulted in further reductions in body weight.^{12,25-27}

For future studies, it might be beneficial to include completion incentives at the end of each phase or at the end of the entire program for both treadmill groups in order to increase exercise adherence rates. Incentives could include water bottles, heart rate monitors, or even t-shirts to further encourage participants to achieve fitness goals and recommendations. The use of music or the availability to watch a television program or movie while walking on the treadmill may also help to enhance the motivational climate and attendance.

Finally, it is recommended to involve more exercise technicians. Additional help would allow more participants to be involved in the study, which would increase the sample size, power of the results, and further validation of the outcomes.

Conclusions

The applicability of this study demonstrated that the walking protocol with the AlterG Anti-Gravity Treadmill was effective to produce significant decreases in weight loss, BMI, and percent body fat in obese individuals. In addition, this study supported the

use of both a traditional treadmill and the AlterG Anti-Gravity Treadmill as effective exercise tools for increasing physical activity in a weight loss program. This was the first study to test the effectiveness of the AlterG Anti-Gravity Treadmill against a traditional treadmill in a weight loss program. Further research is needed to determine the extent of weight loss potential using the AlterG Anti-Gravity Treadmill with an obese population.

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APPENDIX A

Institutional Review Board Approval Letter


BOISE STATE UNIVERSITY

DIVISION OF RESEARCH & ECONOMIC DEVELOPMENT
Office of Research Compliance
 Institutional Review Board
 humansubjects@boisestate.edu | (phone) 208.426.5401 | MS 1138

DATE: June 04, 2013

TO: Shawn R. Simonson (PI)
 Kristi Bercier (co-PI)

FROM: Office of Research Compliance
 Institutional Review Board (IRB)

SUBJECT: IRB Notification of Approval
 Project Title: *Weight Loss Training Protocol Using the AlterG Antigravity Treadmill for Overweight and Obese individuals*

The Boise State University IRB has approved your protocol application. Your protocol is in compliance with this institution's Federal Wide Assurance (#0000097) and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

| | |
|--|---------------------------------------|
| Review Type: Full Board | Approval Number: 103-MED13-004 |
| Date of Approval: June 04, 2013 | Expiration Date: June 03, 2014 |

Your approval is effective for 12 months. If your research is not finished within the allotted year, the protocol must be renewed before expiration date indicated above. The Office of Research Compliance will send a reminder notice approximately 30 days prior to the expiration date. The principal investigator has the primary responsibility to ensure a RENEWAL FORM is submitted in a timely manner. If the protocol is not renewed before the expiration date, a new protocol application must be submitted for IRB review and approval.

Under BSU regulations, each protocol has a three-year life cycle and is allowed two annual renewals. Please note that if your research is not complete by June 03, 2016, a new protocol application must be submitted, rather than a third annual renewal form.

All additions or changes to your approved protocol must also be brought to the attention of the IRB for review and approval before they occur. Complete and submit a MODIFICATION FORM indicating any changes to your project. When your research is complete or discontinued, please submit a FINAL REPORT FORM. An executive summary or other documents with the results of the research may be included.

All relevant forms are available online. If you have any questions or concerns, please contact the Office of Research Compliance, 208-426-5401 or humansubjects@boisestate.edu.

Thank you and good luck with your research.

Dr. Ronald Pfeiffer
 Chairperson
 Boise State University Biomedical Institutional Review Board

APPENDIX B

Recruitment Flyer

RESEARCH PARTICIPANTS NEEDED!

The Human Performance Laboratory at Boise State University needs 40 men and women, aged 18 to 55 years, who would like to lose weight. If you are overweight or obese, based on the diagram below left, we want you for an 18-week weight loss study.



Your involvement will be 3 meetings a week for 20 weeks (an 18-week training program with pre and post assessment weeks).

Participants will walk on a treadmill 3 times a week and wear a pedometer (step counter) on the other days. Some participants will exercise/walk on a standard treadmill and others will use the AlterG Antigravity Treadmill (above right) that supports a portion of their body weight.

All of the information gathered will be kept private and confidential.

A free body composition assessment will be provided at the completion of the study (\$60.00 value). In addition, participants will receive two free subsequent body composition assessments for one year after study completion* (\$120.00 value).

Contact: Kristi Bercier, Graduate Assistant @ (916) 947-5714 or

Kristibercier@u.boisestate.edu

APPENDIX C

Health History Questionnaire Form

Health History Questionnaire

Name: _____ **Date:** _____

Body weight: _____ **Height:** _____ **Birth Date:** _____

1. Gender: Male___ Female___
2. If you are a female, are you pregnant? Yes___ No___
3. General State of Health: Excellent ___ Good ___ Fair ___ Poor ___
4. Presently under the care of a physician? No Yes
5. Month/Year of most recent Physical Exam? ___/___

6. List current medications/drugs (prescription and non-prescription):

(1)._____ (4)._____

None ___ (2)._____ (5)._____

(3)._____ (6)._____

7. List Allergies: Allergy Reaction

(1)._____

None ___ (2)._____

(3)._____

8. Do you have or have ever had: (check all that apply)

| | |
|--------------------------------|----------------------|
| ___Pain in your heart of chest | ___Coughing of blood |
| ___Heart attack | ___Anemia |
| ___Heart murmur | ___Diabetes |

- | | |
|---|--|
| <input type="checkbox"/> Fatigue or lack of energy | <input type="checkbox"/> Epilepsy |
| <input type="checkbox"/> Unusual shortness of breath | <input type="checkbox"/> Bronchitis |
| <input type="checkbox"/> Any heart problem | <input type="checkbox"/> Asthma |
| <input type="checkbox"/> Abnormal EKG | <input type="checkbox"/> Pneumonia |
| <input type="checkbox"/> Extra or skipped heart beats | <input type="checkbox"/> Emphysema |
| <input type="checkbox"/> Elevated cholesterol | <input type="checkbox"/> Abnormal chest x-ray |
| <input type="checkbox"/> Valve problems | <input type="checkbox"/> Other lung diseases |
| <input type="checkbox"/> Diseases of the arteries | <input type="checkbox"/> Migraine or recurring headache |
| <input type="checkbox"/> Varicose veins | <input type="checkbox"/> Rheumatic fever |
| <input type="checkbox"/> Phlebitis | <input type="checkbox"/> Nervous or emotional problems |
| <input type="checkbox"/> Dizziness or fainting spells | <input type="checkbox"/> Injuries to back, arm, legs, joints |
| <input type="checkbox"/> Stroke | <input type="checkbox"/> Back pain |
| <input type="checkbox"/> High blood pressure | <input type="checkbox"/> Swollen, stiff, or painful joints |
| <input type="checkbox"/> Badly swollen ankles | <input type="checkbox"/> Arthritis of arms or legs |
| <input type="checkbox"/> Cough on exertion | <input type="checkbox"/> Scarlet fever |
| <input type="checkbox"/> Hemophilia | <input type="checkbox"/> Currently pregnant |
| <input type="checkbox"/> Other blood diseases | <input type="checkbox"/> Cancer |
| <input type="checkbox"/> Hyperthyroidism | <input type="checkbox"/> Anorexia nervosa |
| | |
| <input type="checkbox"/> Hypothyroidism | <input type="checkbox"/> Bulimia nervosa |
| <input type="checkbox"/> Ulcers | <input type="checkbox"/> Recent surgery |
| | |
| <input type="checkbox"/> Osteoporosis | <input type="checkbox"/> Recent head injury/concussions |
| | |
| <input type="checkbox"/> Hyperlipidemia | <input type="checkbox"/> Fever |
| | |
| <input type="checkbox"/> Current infection | <input type="checkbox"/> Others |

9. Do you have any lower extremity injuries that limit your current mobility?

☐ Yes ☐ No

10. Do you have a close blood relative (parent or sibling) who had a heart attack or sudden death before age 55 (male) or age 65 (female)?

☐ Yes ☐ No

12. Do you currently use tobacco? ☐ Yes ☐ No

11. Please list anything else you feel we should know about you and your current/past health:

APPENDIX D

Informed Consent Form

Boise State University

Department of Kinesiology

Boise State University
1910 University Drive
Boise, Idaho 83725-1710



Weight Loss Training Protocol Using Various Treadmills for Overweight and Obese Individuals

Informed Consent Form

A. Purpose and Background

I _____ (please print), agree to participate in a study entitled "Weight Loss Training Protocol Using the Various Treadmill for Overweight and Obese Individuals" at the Boise State University to obtain information on the effect of weight-supported vs. standard treadmills for weight loss. I understand that I will be randomly selected to participate on either the AlterG Antigravity Treadmill or the traditional treadmill. In this study, I will complete 2 screening questionnaires, have physical measures taken; height, weight, body circumference, skinfolds, heart rate, and blood pressure. The findings of this study may be presented at a conference and/or published in an academic journal. I am willingly, and without reservation, participating in the above-titled study, directed by Kristi Bercier, graduate student, and Dr. Shawn Simonson, faculty, of the Department of Kinesiology.

I am 18 to 55 years old.

B. Procedures

I understand that I will complete the study during the following 55 visits:

Visit 1: Orientation/Informed Consent/Screening (approximately 1 hr)

1. *Orientation contacts:* The investigators will meet with me at the Human Performance Laboratory in the Boise State Bronco Gym building and will present the study's purpose, the protocols and apparatuses that will be utilized. My questions concerning the study will also be answered during this meeting.
2. *Informed consent:* I will read a summary of the study's procedures and sign this informed consent form if I agree to participate in the study. I may withdraw from the study at any time.
3. *Screening:* I understand that to ensure that I will be physically ready for the

study's exercise program, my height, weight, heart rate, and blood pressure will be measured, and I will complete 2 questionnaires: Health History Questionnaire and the Numeric Pain Intensity Scale. Based on the information collected, my eligibility for participation in this study will be determined. It is important that I answer the questionnaires honestly.

Visits 2-55: Physical Measures of 18 week training program

1. I understand that my metabolic rate will be determined during rest, at a moderate speed (1.5 – 3.5 mph) and moderately heavy (70% of my estimated maximum) speed (3.5 – 5.0 mph) at the beginning and at the end of the 18-week weight loss program. I understand that these measures will help to determine my fitness levels and response to the protocol. I also understand that if there are any adverse events during the metabolic testing, that I will be excluded from the study and it will be recommended that I consult my primary care physician.
2. I will pick a regular 3 days of the week and times that will work for me for the entire 18-week training program. I understand that the training program will take place in the Human Performance Lab using the AlterG Antigravity Treadmill or a traditional treadmill under the supervision of the graduate student and trained undergraduate interns. I understand that I will be randomly selected to participate on either the AlterG Antigravity Treadmill or the traditional treadmill.
3. I understand that my heart rate, blood pressure, rating of perceived exertion (RPE, 0-10 scale measuring how hard I am working) and numeric pain scale (NPS, 0-10 scale measuring my pain level) scores will be recorded multiple times per each exercise session.
4. I understand that every 6 weeks (beginning, week 6, week 12, and week 18) I will come into the Human Performance Lab for body composition testing. I understand that during these sessions, my blood pressure, heart rate, waist to hip ratio, calf circumference and Jackson-Pollock 7-site skinfold measurements will be measured and recorded.
5. I understand that I will be required to keep a written exercise log for the sole purpose of program adherence and use as a motivational tool. The exercise log has specific questions for me to answer and I understand that I will turn in this log at the end of each week. I understand that no data will be collected from this exercise log. If I decide to keep my exercise log at the completion of the study, I will be given a copy for my own records.
6. Lastly, I understand that I will be loaned a pedometer to use during the duration of the 18-week study. I understand that the pedometer will be used to measure outside physical activity only and will not be worn while I am exercising on the treadmill, in the shower or sleeping. I understand that the exercise technician will ask the number of steps I walked for the previous day during each exercise

session. I will return the pedometer at the end of the study.

C. Risks/Discomforts

Body composition measures: Measuring various body sizes and dimensions may cause psychological discomfort. Some slight discomfort may be experienced while using the AlterG Antigravity or traditional treadmills. The researchers are sensitive to these issues and will strive to optimize the research experience to make me comfortable.

Physical injury: Possible risks for physical activity and exercise include injury (such as muscular strain), overexertion (leading to fatigue, nausea, headaches, shortness of breath), and a temporary increase in systolic blood pressure. Researchers will carefully monitor me during my participation to minimize these risks. In the event I become sick or injured during the course of the research study, I will immediately notify my personal physician and the principal investigator.

D. Benefits

Potential benefits expected as a result of my participation have been explained to me, and include: (a) weight loss, (b) A better understanding of the impact of body fat for overweight adults (b) a better understanding of appropriate and safe weight loss (c) better understanding of physical intensity level of physical and daily activities; and (e) free body composition assessments.

Potential benefits to the larger community include an understanding of the use of a body-weight supporting treadmill in weight loss and weight management.

E. Confidentiality

Reasonable efforts will be made to keep the personal information in my research record private and confidential. Any identifiable information obtained in connection with this study will remain confidential and will be disclosed only with my permission or as required by law. The information obtained from this study may be used for a statistical or scientific purpose with my right of privacy upheld. I understand that due to the make-up of Idaho's population, the combined answers to some questions in questionnaires regarding gender, age race and ethnicity, may make an individual person identifiable. Every effort will be taken by the researchers to protect my confidentiality. However, if I am uncomfortable answering any of these questions I may leave them blank.

F. Payment/Compensation

I understand that there will be no payment for my participation in this study. In addition to receiving a free body composition assessment at completion of the study (\$60.00 value), I will receive two free subsequent body composition assessments for one year after study completion* (\$120.00 value; *Non-transferrable and limited to every other month).

G. Questions/Voluntary Participation/Withdrawal

I may withdraw from this study at any time without penalty. The decision to participate,

decline, or withdraw participation will have no effect on my relationship with Boise State University. I have been given an opportunity to ask questions concerning the information given to me. I understand that I may contact Dr. Shawn Simonson at (208) 426-3973 or ShawnSimonson@boisestate.edu, or the Boise State Institutional Review Board at (208) 426-5401 between 8:00 AM and 5:00 PM, Monday through Friday or Institutional Review Board, Office of Research Compliance, Boise State University, 1910 University Dr., Boise, ID 83725-1138.

H. Consent

I have read, or have had read to me, all of the above information about this research study, including the research procedure, possible risks, and the likelihood of any benefits to me. My questions have been satisfactorily answered. I hereby consent and voluntarily offer to follow the study requirements and take part in the study.

I will receive a signed copy of this form.

| | | |
|-------------|--------------|-------|
| _____ | _____ | _____ |
| Participant | Printed Name | Date |

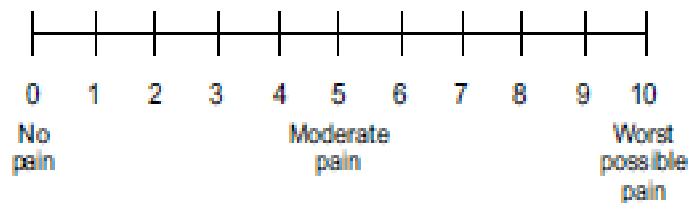
| | | |
|------------|--------------|-------|
| _____ | _____ | _____ |
| Researcher | Printed Name | Date |

APPENDIX E

Numeric Pain Scale Form

Patient Name: _____ Date: _____

0-10 Numeric Pain Intensity Scale*



*If used as a graphic rating scale, a 10-cm baseline is recommended.

From: Acute Pain Management: Operative or Medical Procedures and Trauma, Clinical Practice Guideline No. 1. AHCPR Publication No. 92-0032; February 1992. Agency for Healthcare Research & Quality, Rockville, MD; pages 116-117.